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APPLICATION NO.	F	LING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
10/033,055	12/27/2001		Ronald M. Burch	200.1079CON	7860	
23280	7590	07/28/2006		EXAMINER		
		DSON & KAPPEL	LIU, SUE XU			
485 SEVENTH AVENUE, 14TH FLOOR NEW YORK, NY 10018			ART UNIT	PAPER NUMBER		
	,			1639		

DATE MAILED: 07/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)	
	10/033,055	BURCH ET AL.	
Office Action Summary	Examiner	Art Unit	_
	Sue Liu	1639	
The MAILING DATE of this communication a Period for Reply	ppears on the cover sheet with	the correspondence address	_
A SHORTENED STATUTORY PERIOD FOR REF WHICHEVER IS LONGER, FROM THE MAILING  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period.  - Failure to reply within the set or extended period for reply will, by stat Any reply received by the Office later than three months after the mai earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATION OF THIS COMMUNICA	ATION.  by be timely filed  IS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).	
Status			
1) ☐ Responsive to communication(s) filed on 11 2a) ☐ This action is FINAL. 2b) ☐ The 3) ☐ Since this application is in condition for allow closed in accordance with the practice under the second sec	nis action is non-final. vance except for formal matter		
Disposition of Claims			
4) ☐ Claim(s) 38 and 47-56 is/are pending in the 4a) Of the above claim(s) is/are withden 5) ☐ Claim(s) is/are allowed. 6) ☐ Claim(s) 38 and 47-56 is/are rejected. 7) ☐ Claim(s) is/are objected to. 8) ☐ Claim(s) are subject to restriction and	rawn from consideration.		
Application Papers			
9) The specification is objected to by the Exami 10) The drawing(s) filed on is/are: a) and an applicant may not request that any objection to the Replacement drawing sheet(s) including the correction.  11) The oath or declaration is objected to by the	ccepted or b) objected to by ne drawing(s) be held in abeyance ection is required if the drawing(s	e. See 37 CFR 1.85(a). is objected to. See 37 CFR 1.121(d).	
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:  1. Certified copies of the priority docume 2. Certified copies of the priority docume 3. Copies of the certified copies of the priority docume application from the International Bure * See the attached detailed Office action for a life.	ents have been received. ents have been received in Apriority documents have been received in Received	olication No eceived in this National Stage	
Attachment(s)  1)  Notice of References Cited (PTO-892)	4) ☐ Interview Su	mmary (PTO-413)	
Notice of Draftsperson's Patent Drawing Review (PTO-948)     Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0 Paper No(s)/Mail Date	Paper No(s)/	Mail Date ormal Patent Application (PTO-152)	

#### **DETAILED ACTION**

Please note the change of examiner for this application. (Please see the Conclusion paragraph for information on any future correspondence.)

#### **Claim Status**

Claims 1-37 and 39-46 have been cancelled;

Claims 38, and 47-56 are currently pending;

Claims 38, and 47-56 are being examined in this application.

## **Priority**

1. This application is a continuation of 09/154,354 (filed 9/17/1998; now US Patent 6,552,031), which claims benefit of 60/059,195 (filed 9/17/1997).

### Claim Rejections Maintained (103 art rejection)

### Claim Rejections - 35 USC § 103

- 2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- 3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c)

4. 7. Claims 38, 47-48, and 50-56 as amended or originally filed are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 4,569,937 (Baker et al) and Penning et al (J. Med. Chem. 1997, 40, 1347-1365). The previous rejection is maintained for the reasons of record advanced on pages (2-5) of the office action mailed on 10/6/05.

## Discussion and Answer to Argument (103 art rejection)

5. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants emphasize that because the claim language is drawn to using analysesic compounds consisting essentially of two particular agents, the claim exclude any other analysesic compound.

To answer applicant's argument regarding claim interpretation, contrary to applicant's assertion, the phrase "consisting essentially of" is not a close-ended transitional phrase that excludes any other materials that are not recited in the claim. On the other hand, the MPEP defines the phrase "consisting essentially of" as the following (see MPEP 2111.03 [R-3] Transitional Phrases):

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original) (Prior art

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hydraulic fluid required a dispersant which appellants argued was excluded from claims limited to a functional fluid "consisting essentially of" certain components. In finding the claims did not exclude the prior art dispersant, the court noted that appellants' specification indicated the claimed composition can contain any wellknown additive such as a dispersant, and there was no evidence that the presence of a dispersant would materially affect the basic and novel characteristic of the claimed invention. The prior art composition had the same basic and novel characteristic (increased oxidation resistance) as well as additional enhanced detergent and dispersant characteristics.). "A consisting essentially of claim occupies a middle ground between closed claims that are written in a consisting of' format and fully open claims that are drafted in a comprising' format." PPG Industries v. Guardian Industries, 156 F.3d 1351, 1354, 48 USPQ2d 1351, 1353-54 (Fed. Cir. 1998). See also Atlas Powder v. E.I. duPont de Nemours & Co., 750 F.2d 1569, 224 USPQ 409 (Fed. Cir. 1984); In re Janakirama-Rao, 317 F.2d 951, 137 USPO 893 (CCPA 1963); Water Technologies Corp. vs. Calco, Ltd., 850 F.2d 660, 7 USPQ2d 1097 (Fed. Cir. 1988). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, e.g., PPG, 156 F.3d at 1355, 48 USPQ2d at 1355 ("PPG could have defined the scope of the phrase consisting essentially of' for purposes of its patent by making clear in its specification what it regarded as constituting a material change in the basic and novel characteristics of the invention."). See also AK Steel Corp. v. Sollac, 344 F.3d 1234, 1240-41, 68 USPQ2d 1280, 1283-84 (Fed. Cir. 2003) (Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.); In re Janakirama-Rao, 317 F.2d 951, 954, 137 USPQ 893, 895-96 (CCPA 1963). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPO2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus excluded the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish

that a step practiced in a prior art method is excluded from his claims by consisting essentially of language.").

In addition, the claim language is drawn to a method of "administering to a human patient an oral dosage <u>comprising</u> analysis compounds consisting ensentially of...". The transitional phrase, "comprising" renders the claim open-ended, and therefore the claimed oral dosage would not exclude other materials or substances.

Applicants also argue that the rejection based on the Baker reference is unfounded (top of pg 5, Applicant's reply).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Applicants also argue that the Baker reference is directed to pharmaceutical compositions of narcotic analgesics and ibuprofen, but not compositions comprising other members of the broad class of NSAIDs (non-steroidal anti-inflammatory drugs) that are different from ibuprofen. Specifically, applicants argue that the Baker reference only mentioned the term "NSAID" twice in Cols. 1-2 of the Baker's reference. And the teaching of NSAID in Cols. 1-2 is a discussion of prior art, not a teaching of the Baker reference.

The examiner respectfully disagrees. Regardless of the number of times the acronym "NSAID" is mentioned in the text of the reference, the Baker reference teaches the class of drugs that are known as NSAID, as recited in Col. 1-2 of Baker.

Although Baker does not specifically teach a combination of a narcotic analgesic such as oxycodone and a NSAID such as celecoxib, Baker teaches the advantages such as enhanced analgesic effect by combining narcotic analgesics and NSAID in general (see Col. 1, lines 21+, for example). This provides motivations for combining any narcotic analgesic and NSAID that would provide enhanced analgesic effect. The outstanding 103 rejection cited above is over a combination of references, but not over Baker alone. The combination of references teaches the combination of oxycodone and celecoxib as discussed below.

In addition, applicant's argument of the teachings recited in col.1-2 of the Baker reference is a discussion of prior art, but not a teaching of the Baker reference, is also addressed in the previous office action, and is incorporated below:

Applicant's interpretation of the Baker patent reference fails to consider the Baker patent teaching as a whole to one of ordinary skill in the art:

"The use of patents as references is not limited to what the patentees describe as their own inventions or to the problems with which they are concerned. They are part of the literature of the art, relevant for all they contain." In re Heck, 699 F.2d 1331, 1332-33, 216 USPQ 1038, 1039 (Fed. Cir. 1983) (quoting In re Lemelson, 397 F.2d 1006, 1009, 158 USPQ 275, 277 (CCPA 1968)). A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. Merck & Co. v. Biocraft Laboratories, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also Celeritas Technologies Ltd. v. Rockwell International Corp., 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998).

Accordingly, the Baker teaching includes Baker's entire specification and claims, inclusive of Baker's summary of the state of the prior art as illustrated in the "The Background of the Invention" (col. 1-2). In this respect, Baker '936 (col. 1-2) cites numerous prior art references starting with Sunshine et al. for the premise of making analgesic compositions by combining NSAID's with narcotic analgesic (distinguished by merely additive analgesic effect) as well as other NSAID's (e.g. acetaminophen etc) with various narcotic analgesics, most notably oxycodone. Baker's invention (e.g. following the summary) is distinguished from the prior art by selecting compositions comprising ibuprofen as the NSAID in combination with narcotic analgesics (including oxycodone) in synergistically effective amounts while reducing the amounts of the narcotic analgesic thus addressing the problem of addiction (pointed to at the end of the "Background of the Invention").

Applicants also argue that the Baker reference rejected all NSAIDs in their invention except ibuprofen (pg5, 3<sup>rd</sup> para. of applicant's reply). Applicants also argue that the Baker reference teaches away from substituting ibuprofen with another NSAID, because of the unexpected synergy that it purports for the combination of ibuprofen with a narcotic analgesic (pg6, 2<sup>nd</sup> para).

In support of applicant's argument that the Baker reference rejected all NSAIDs in their invention except ibuprofen by quoting col. 1, lines 6-9 and col. 2, lines 11-15 of the Baker disclosure:

This invention relates to pharmaceutical compositions of narcotic analgesics and ibuprofen having analgesic activity in mammals, and to methods

of use of the compositions to alleviate pain in mammals. (Emphasis Added by applicants)

According to the present invention there is provided a pharmaceutical composition comprising a combination of (a) a narcotic analgesic, or a pharmaceutically acceptable salt thereof and (b) <u>ibuprofen</u>. or a pharmaceutically suitable salt thereof, ... (Emphasis Added by applicants)

Contrary to applicant's interpretations of the disclosure, the Baker reference does not reject all or teach away from other NSAIDs. The quoted paragraphs from the disclosure only provide one aspect of the reference's teachings of a particular combination of narcotic analgesics and ibuprofen. As discussed above, Baker et al teaches combinations of narcotic analgesics and NSAIDs (see col. 1-2), and do not exclude other NSAIDs from forming the combination of narcotic analgesic and NSAID that would have enhanced analgesic effect. In other words, the Baker reference does not teach that a combination of a narcotic analgesic and any of the other NSAIDs (besides ibuprofen) cannot be made or cannot be used to treat pain.

Rather, the Baker reference opens the door for developing combinations of NSAIDs and narcotic analgesics beside the combinations of ibuprofen and oxycodone. As discussed above, Baker teaches, in general, a combination of a selected NSAID and a narcotic analgesic would have enhanced analgesic effect (col. 1, lines 22+). Baker et al also demonstrated a particular combination of the two classes of drug has enhanced analgesic effect. A person of ordinary skill in the art would be motivated to select different NSAID and/or a different narcotic analgesic to form a desired combination with enhanced analgesic effect.

In addition, applicant's "teaching away" argument was also addressed in the previous office action, and the relevant section from the previous office action is cited below:

In light of the "Background of the Invention" of the Baker reference (e.g. Col. 1-2) and lack of any evidence that substitution with a different NSAID would render pain treatment inoperative applicant's teaching away argument is not understood. At most, the selection of a different NSAID may lead to less than synergistic pain relief (e.g. additive) and as such may be "less preferred". In this regard, however, it is noted that:

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. In re Susi, 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." In re Gurley, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). See also MPEP 2121.04.

Applicants also argue that the examiner has improperly picked and chosen the celecoxib of the Penning references with the oxycodone of Baker to recreate the instant claims. Applicants' also argue that by modifying the formulation of the Baker reference in view of the Penning reference through substituting ibuprofen with celecoxib would result in a dosage form which is not directed to the principle of operation described in Baker et al. (Applicants cited MPEP 8<sup>th</sup> ed. Revision 2, p.2100-132 for "the principle of operation" argument.)

Contrary to applicants' assertion, the references are properly combined because the combination of the reference teaches or suggests all elements of the instant claims, teaches motivation to combine the references' teachings, and demonstrates reasonable expectation of success. Because applicants do not dispute that the cited references teach all elements and reasonable expectation of success, the discussion below is only addressing applicants' arguments over the motivation to combine the references' teachings (in addition to the reason of record):

First, applicant's citation of the MPEP is irrelevant. In MPEP 2143.02, the manual states "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims prima facie obvious." The manual also cites *In re Ratti*, 270 F. 2d 810, 123 USPQ 349 (CCPA 1959). *In re Ratti was directed to a claim drawn to* "an oil seal comprising a bore engaging portion with outwardly biased **resilient** spring fingers inserted in a **resilient** sealing member". The court held that a secondary reference requiring a complete redesign of the primary reference oil seal from one which **required rigidity** to one which was **resilient** was not combinable (emphasis provided). That is the combination of references cited in the case requires complete redesign of the oil seal from the primary reference.

In the instant situation, however, the modification (or substitution) of the analgesic combination is through replacement of one functionally equivalent compound for another, and is useful for the same purpose of treating pain.

Additionally, applicant's interpretation of the "principle of operation" of the Baker reference teaching is too narrow. The "principle of operation" of the Baker reference is to combine NSAID's (e.g. ibuprofen) with opioids (e.g. oxycodone) in order to achieve improved pain relief as compared to the separate administration of the active agents. The unexpected benefit of achieving greater than additive pain relief (e.g. synergism) represents a strong teaching toward formulating additional compositions which include different (functionally equivalent) NSAID's, especially those with fewer side-effects as compared to traditional NSAID's as pointed out in the secondary reference (Penning et al; e.g. pg 1347 of the reference).

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In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the above rejection provides ample motivation to combine the references *inter alia* the substitution of one non-narcotic NSAID for another, especially where the secondary reference suggests benefits imparted by making the substitution as outlined in the rejection set forth in the previous office action. For the sake of clarity, the motivation supplied by each of the reference and the reason to combine the references are stated below:

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Baker et al. teach pharmaceutical compositions for relieving pain in humans or mammals (e.g. mice, rats etc.) comprising a combination of:

- a. a narcotic analgesic (preferably oxycodone: see formulations col. 4-8; mice data in col.
  8-10; patent claims), or a pharmaceutically acceptable salt thereof; and
- b. ibuprofen (a non-steroidal anti-inflammatory drug or <u>NSAID</u>: see col. 1-2), or a pharmaceutically acceptable suitable salt thereof.

The Baker et al. reference teach that dose ratios can be adjusted and that the analgesic activity of the combined oxycodone and ibuprofen activity is unexpectedly enhanced or synergistic i.e. the resulting activity is greater than the activity expected from the sum of the activities of the individual components, thereby permitting reduced dosages of narcotic analgesics (e.g. oxycodone) AND which diminishes adverse side effects (e.g. addiction) and

toxicity which would result from the otherwise required amounts of the individual drug components resulting from high dosages of oxycodone or NSAID's such as ibuprofen. See e.g. col. 1-2; col. 3, lines 19-32). Accordingly, Baker would teach the use of therapeutic and subtherapeutic amounts of oxycodone and/or ibuprofen in view of the synergistic nature of the combinations and the desire to reduce the toxicity and/or side-effects of both agents; and as required by the doctor for his/her particular patient., including dosage optimization e.g. dosage overlapping of active ingredients. See e.g. col. 3 where dosage is modified to suit the particular patient.

The Baker analgesic composition differs from that presently claimed in that it fails to teach the substitution of celecoxib for ibuprofen into the Baker compositions.

**Penning et al** teach both *in vitro* and *in vivo* (up to phase 2 clinical trials) that the selective COX2 inhibitor celecoxib (SC-58635):

- a. had potent anti-inflammatory activity equivalent to NSAID's without the gastric toxicity side-effect of the NSAID's (e.g. celecoxib had no acute GI toxicity in rats at doses of up to 200 mg/kg and no chronic GI toxicity at doses up to 600 mg/kg);
  - b. has good bioavailability, is well distributed, and has an excellent safety profile;
- c. is at least as potent against pain as aspirin in a phase 1 human clinical dental pain study.

See Penning abstract; page 1347; pages 1352-1354; Tables1-10.

Accordingly, one of ordinary skill in the art would have been motivated to substitute celecoxib for ibuprofen in the Baker reference compositions in light of the Penning reference

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teaching that celecoxib is analgesically potent with less side effects (e.g. as compared to

NSAIDS e.g ibuprofen) in both in vitro and in vivo models, including humans.

Additionally, it is noted that the instant situation is amenable to the type of analysis set

forth in In re Kerkhoven, 205 USPQ 1069 (CCPA 1980) wherein the court held that it is prima

facie obvious to combine two (or more) compositions each of which is taught by the prior art to

be useful for the same purpose.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time

of applicant's invention to modify the Baker reference analgesic composition by substituting

celecoxib for ibuprofen in Bakers composition in light of the benefits of celecoxib (potent

analgesia/decreased side effect as compared to NSAID e.g. ibuprofen) as taught by the Penning

reference.

Claim Rejections Maintained (103 art rejection)

Claim Rejections - 35 USC § 103

6. Claim 49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Baker et al. '937

and Penning et al as applied to claims 38, 46-48 and 50-56 above, and further in view of Oshlack

et al. US Pat. No. 5,472,712 (12/95) or Oshlack et al. US Pat. No. 6,294,195 (9/01: effectively

filed 10/93 or earlier). The previous rejection is maintained for the reasons of record advanced on

pages (5-6) of the office action mailed on 10/6/05.

Discussion and Answer to Argument (103 art rejection)

7. Applicant's arguments have been fully considered but they are not persuasive for the following reasons (in addition to reasons of record). Each point of applicant's traversal is addressed below (applicant's arguments are in italic):

Applicants briefly argue that "the Oshlack references do not cure the deficiencies of the Baker reference in view of the Penning references as set forth above" (pg 7, 4<sup>th</sup> para.).

Because applicant did not provide explanation as to why the Oshlack reference do not cure the deficiencies of the Baker reference in view of the Penning reference, the previous rejection is maintained for the reason of record, and the rejection is herein incorporated by reference in its entirety.

Applicant's argument can also be construed to be over the Baker reference, which is addressed in the above discussion.

#### Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing

date of this final action.

Any inquiry concerning this communication or earlier communications from the

examiner should be directed to Sue Liu whose telephone number is 571-272-5539. The

examiner can normally be reached on M-F 9am-3pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's

supervisor, Peter Paras can be reached at 571-272-4517. The fax phone number for the

organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent

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PETER PARAS, JR. SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600

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